The applicants also note the Examiner's remarks concerning the preferred form of the specification. In that regard, the applicants invite the Examiner's attention to the heading "Brief Description of the Drawings" on page 42 of the specification.

Turning to substantive matters, Claims 1-5 stand rejected as being clearly anticipated by *Kitajima* (5,460,777) or *Makino* (5,393,493). The applicants respectfully traverse those rejections, for the reasons set forth below.

Present Invention

A dry measuring test device according to the present invention, as defined in Claim 1, comprises a reagent layer including a reagent containing a chromogen and a matrix having the reagent in the form of a layer, for determining a substance to be measured in a liquid sample by measuring the degree of coloring of the chromogen generated through the reaction between the substance and the reagent. This measurement takes place in terms of reflectance of light entered into the reagent layer. The reagent layer comprises polymer beads embedding in light-reflective particles.

Conventionally, in such dry measuring test devices to detect a substance in a liquid sample through the coloring reaction between the substance and a reagent, an attempt was made to enhance measurement precision by having the light-reflective particles directly contained in the reagent layer and to have the reagent for coloring contained therein as well. However, if a large amount of light-reflective particles is contained to improve measurement precision, the reagent layer becomes so dense that a liquid sample can hardly penetrate and develop, and it takes a long time until the amount of the coloring matter generated by the reaction by the reagent becomes sufficiently measurable. This is a problem in practical use of the conventional dry-measuring test devices. Furthermore, it is disadvantageous in that the measurement precision may possibly be lowered due to dryness if the measuring time is prolonged as described above.

The Present Invention

The dry measuring test device according to the present invention has a reagent layer that does not directly contain the light-reflective particles. Instead, the test device uses polymer beads embedding light-reflective particles, to solve the problems described above. The dry measuring test device of the present invention can contain a large amount of light-reflective particles in the reagent layer in the form of polymer beads embedding those particles with such a structure that the measuring time is relatively short, thereby reducing the influence of dryness.

The Cited References vs. the Present Invention

(1) Kitajima

Kitajima discloses an analytical element for whole blood analysis and teaches various constructions of the analytical element. Among them is an analytical element having a light-shielding layer containing particulates having light-shielding ability, or light-shielding and light-reflecting ability, (hereinafter referred to as "light-shielding particulates") as a constructional element (col. 9, line 24-54). Kitajima further discloses that the light-shield layer is a water-permeable layer where the light-shielding particulates are dispersed in and supported by a small amount of hydrophilic polymer binder having film-forming ability. From this description, it is clear that the light-shielding particulates are dispersed in the form of the particulates per se in the hydrophilic polymer film. Furthermore, the light-shielding layer described in Kitajima is an independent layer which is separated from the reagent layer.

However, there is <u>no description</u> in *Kitajima* that the reagent layer comprised polymer beads embedding light-reflected particles, which is an element of the present invention as

defined in Claim 1. Moreover, *Kitajima* does not suggest the claimed construction of the reagent layer in a dry measuring test device.

(2) Makino

Makino discloses a dry-type analytical element for whole blood. In col. 4, lines 18-33, Makino discloses that reflective particles may be incorporated into the fibrous layer, the nonfibrous porous layer, the nonporous reagent layer, or the like, which consists of the analytical element for whole blood. Further, Makino mentions that when the light-reflective particles are incorporated into the fibrous layer, the particles may be disbursed in the layer using a hydrophilic polymer binder such as gelatin, gelatin derivatives, cellulose derivatives, agarose, polyacrylamide, polymethacrylamide, and copolymers of polyacrylamide or polymethacrylamide and various vinyl monomers. However, Makino does not describe a method for incorporating the light-reflecting particles into the nonfibrous porous layer, the nonporous reagent layer, or the like. Therefore, there is no description in Makino of a reagent layer comprising polymer beads embedding light-reflective particles, which is a feature of the claimed invention, nor any suggestion as to the overall structural and functional combination of the reagent layer for a dry measuring test device as claimed herein.

Summarizing the foregoing discussions, because *Kitajima* and *Makino* do not disclose the reagent layer comprising polymer beads embedding light-reflective particles, as recited in Claims 1, et al., the claims are not anticipated by those references. Therefore, the rejection of Claims 1-5 under 35 U.S.C. 102(b) should be withdrawn.

The foregoing is submitted as a complete response to the Office action identified above. The applicant submits that the present application is in condition for allowance and requests a notice to that effect.

Respectfully submitted,

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ABSTRACT OF THE DISCLOSURE

Determining a substance to be measured in a liquid sample by measuring the degree of coloring obtained when the substance is subjected to coloring reaction in terms of reflectance. Polymer beads embedding light reflective particles are contained in a reagent layer of the dry measuring test device, or a light blocking layer containing light blocking particles, preferably polymer beads embedding the light blocking particles, is laminated on the reagent layer of the dry measuring test device. The reagent layer comprises a reagent containing a chromogen and a matrix which retains the reagent in the form of a layer, for determining the substance to be measured in the liquid sample by measuring the degree of coloring of the chromogen generated through the reaction between the substance and the reagent in terms of reflectance of light entered into the reagent layer. Speedy and highly accurate measurement is obtained in shortening measuring time by measuring reflectance corresponding to a low degree of coloring or by reducing influence of solid matter contained in the liquid sample on absorption and scattering of the measuring light and influence of external stray light entered from the opposite side of the surface of the light measuring part.

App. No. 08/959,125 Docket No. 20111-0014